



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,458	12/21/2000	Jorg G. Moser	BJA272C	3984

7590 02/07/2006

BOLESH J. SKUTNIK PhD,JD
515A Shaker Road
East Longmeadow, MA 01028

EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,458

Applicant(s)

MOSER, JORG G.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3-4, 7, 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8 and 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In the response, filed 5-17-02, Applicants elected a parachute structure of “cyclodextran.” The therapeutic component was chosen to a photosensitizer such as porphyrin. Applicants also chose the spacer as a beta-amino acid or gamma-amino acid.

A search was conducted for the elected species of cyclodextran with porphyrin and prior art was found that anticipated the species. Claims 1-2, 5-6, 8, 12-18 read on the elected species.

Claims 3-4, 7, 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-2, 5-6, 8, 12-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the claim seems incomplete with respect to “preselected defined distance from the membrane within cells” since it is unclear what role the complex plays in the defining this distance. The claims do indicate if the complex maintains or limits the defined distance.

In claim 2 it is unclear what is a defined action diameter. Does the claim intend a specific diameter for the hydrophilic moiety? If so then such a diameter should be recited in the claim.

Art Unit: 1654

Without this information, one cannot readily ascertain if a hydrophilic moiety possesses the desired defined action diameter limitation of the claim.

In claim 2, it stated that "said hydrophilic moieties are preferably sugar residues." It is unclear if the claims is limited to the "preferably" hydrophilic moieties that sugar residues or is open to other hydrophilic moieties.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-6, 8, 12-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

Art Unit: 1654

"such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ('In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .'). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See

Art Unit: 1654

MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to complex comprising “at least one parachute structure, having a pre-selected defined action diameter which hinders said structure from penetrating through a cell membrane, and at least one therapeutic compound, which can penetrate said cell membrane.” The generic statements parachute structure or therapeutic agent does not provide ample written description for the compounds since the claims do not describe a single structural feature. In fact a parachute structure, since the terminology is not used in organic chemistry, does not exemplify any molecule that contains a carbon atom. Note that the function of “preselected defined action diameter” also does not provide insight into the structure since the “said action diameter is defined by the structure of branching units to which said hydrophilic moieties are bound and the length and structure of said hydrophilic moieties.” The parachute structure comprising hydrophilic moieties. Thus, without knowing the parachute structure, does not know the “preselected defined action diameter.”

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of polymer with any biomolecule. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining

Art Unit: 1654

the claimed sequence.” MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Although the specification does provide examples of what qualify as compounds of the claimed invention, which are limited to a single embodiment in example 1 which is cyclodextran conjugated to bacteriopheophorbide, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples beyond cyclodextran conjugated to bacteriopheophorbide. The specification is void of any peptides, organic molecules that qualify for the functional characteristics claimed as parachute structures. The specification is limited defining parachute structure as glucosamine and cyclodextrin. There is no disclosure other compounds that qualify as parachute structures. The specification states that “parachute function may be achieved by other, more bulky hydrophilic structures such as oligosaccharides connected to the branching unit,” but does not exemplify these “bulky hydrophilic structures. The specification is replete generic definitions without specific examples. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 8, 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruebner et al.

The claims are drawn to a complex comprising a parachute structure, that is a cyclodextran, and a therapeutic compound that is porphyrin.

The reference disclose cyclodextrin dimers conjugated to porphyrins such as ter-butylphenoxy-ethy-pyropheophorbide-ethyl ester or tri-tert-butylphenoxy-monosulfophenoxy-pthalocyanine (see page 37). The reference states that cyclodextrin dimers bound to porphyrinoid derivatives are suitable for photosensitizers in Photodynamic therapy. Photodynamic therapy (PDT) is also called photoradiation therapy, phototherapy, or photochemotherapy. It involves using a drug called a photosensitizing agent, which is activated by being exposed to light, to destroy cancer cells.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 1654

F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1-2, 5-6, 8, 12-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 6,806,28. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

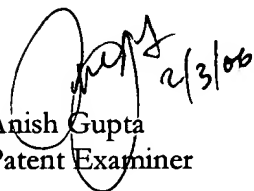
The US patent claims "A complex for delivery and application of drugs to cells at their membranes comprising: a parachute structure, having a preselected action diameter; a therapeutic compound, being a photosensitizer; wherein said parachute structure is two hydrophilic moieties attached to a branching unit, defining said preselected action diameter; wherein said branching unit connects said hydrophilic moieties and said therapeutic compound and is selected from the group consisting of triazine trichloride and trimesinic acid trichloride; herein said photosensitizer is chosen from the group consisting of bacteriopheophorbide and pheophorbide; and wherein said two hydrophilic moieties are glucosamines" (see claim 1). The US patent also claims spacer, wherein said spacer is a molecule selected from the group consisting of beta-amino acids and gamma-amino butyric acid and is also bonded to said therapeutic compound, thus completing the connection between said branching unit and said therapeutic compound (see claim 2). Note that the spacers claimed are similar to the spacers claimed in 9-11 of the instant application. The difference between

Art Unit: 1654

the US Patent and the instant claims is that the US Patent claims are specific while the instant claims are a genus.

However, "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. Thus, the claimed invention is not patentably distinct from the invention of the US patent.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

 2/3/06
Anish Gupta
Patent Examiner